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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,114	03/22/2001	Michael L. Boyer II	8932-208-999	2083
20582	7590	10/16/2003	EXAMINER	
PENNIE & EDMONDS LLP 1667 K STREET NW SUITE 1000 WASHINGTON, DC 20006			HAMILTON, LALITA M	
			ART UNIT	PAPER NUMBER
			3624	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/814,114

Applicant(s)

BOYER ET AL.

Examiner

Lalita M Hamilton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on RCE filed on September 22, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-54 and 56-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-54 and 56-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Request for Continued Examination***

The request filed on September 22, 2003 for a Request for Continued Examination is acceptable and a RCE has been established. An action on the RCE follows.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 5-11, 14-15, 17-22, 25-30, 33-39, and 77-78 are rejected under 35 U.S.C. 102(a) as being anticipated by Boyce (5,899,939).

Boyce discloses an implant comprising inner and outer sheaths formed from different bone wherein the exterior surface of the outer sheath contacts the interior surface of no more than one other sheath (fig.2: 22 and 23), the contacting surfaces of adjacent sheath being machined surfaces (col.4, lines 47-52), at least one sheath packing bone growth materials (col.2, lines 35-40 and col.5, lines 18-20), two layers of bone components coupled to each other at a securing region and at least one insertable securing element (col.4, lines 10-20), the outer surface separated from a portion of the inner surface, the sheath comprising alignment indicia (mechanically interengaging features) (col.4, lines 14-20), two ring-shaped members formed from bone that are coupled together to

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define a central opening (col.6, lines 1-20), a supplemental annular surfaces selected from metals, alloys, ceramics, polymers, and composites (col.6, lines 1-10), the central opening packed with at least one of bone material and bone inducing substances (col.4, lines 53-61), and the ring-shaped members being press-fit together (col.4, lines 1-20).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56-57, 60, 62-66, 69-70, and 74-76 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boyce.

Boyce discloses an implant comprising a body having two annular members and at least one inner annular member, at least one of the annular members is formed from bone and the annular members are coupled together to define a central opening (fig.2 and col.6, lines 1-20), each annular member having at least one surface that is press-fit with another surface (col.4, lines 1-20), the bones comprising one of autograft, allograft, and xenograft bone tissue (col.1, line 19 and col.3, lines 40-45), bone tissue of at least one bone is partially demineralized or demineralized (col.3, lines 40-45), at least one fastener being a screw or pin (col.4, lines 1-20), a bonding agent (col.4, lines 1-20), contacting

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surfaces being machined surfaces (col.4, lines 1-20), press-fitting (col.4, lines 1-20), a supplemental annular surfaces selected from metals, alloys, ceramics, polymers, and composites (col.6, lines 1-10), the central opening packed with at least one of bone material and bone inducing substances (col.4, lines 53-61) alignment indicia (col.4, lines 1-20), and adjacent surfaces not completely contacting one another.

Claims 12-13, 31-32, 58-59, 67-68 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce.

Boyce discloses the invention substantially as claimed and further discloses that the layers may be assembled by a variety of means (col.4, lines 1-20). It is inherent, and therefore, obvious, that at least one of the sheaths may be at least partially dehydrated to fit within a surrounding sheath having a greater moisture content. Further, Boyce discloses that the implant may be formed into any desired shape or dimension. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the annular member in a non-circular or generally oblong shape and to form the diameter of the outer annular member smaller than the diameter of the inner annular member as alternative shapes for the device depending on where it is to be implanted.d

Claims 3-4, 16, 23-24, 35, 40-54, 61, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce in view of McIntyre (4,950,296).

Boyce discloses the invention substantially as claimed; however, Boyce does not disclose cancellous bone or bone selected from the femur, tibia,

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humerus, fibula, ulna, and radius. McIntyre teaches a bone implant comprising cancellous bone (col.3, lines 15-16) and bones selected from the femur, tibia, humerus, ulna, fibula, and radius (col.2, lines 52-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate cancellous bone and bones selected from the femur, tibia, humerus, fibula, ulna, and radius, as taught by McIntyre into the device disclosed by Boyce, as alternative sources of bone.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-54 and 56-78 have been considered but are moot in view of the new ground(s) of rejection.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).


The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2272.



LMH



HANI M. KAZIMI  
PRIMARY EXAMINER